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It is our great pleasure to present this Supplement Issue on “*Macedonian Pharmaceutical Bulletin*” to the scientific and professional community. This supplement includes the short communications from the *Sixth Congress of Pharmacy in Macedonia with International participation*, as the largest gathering for the pharmacy profession held in the Republic of Macedonia. The main theme of the Congress was “Modern pharmacist - bridging science with practice”.

A broad spectrum of topics within the pharmaceutical sciences and practice carefully selected for this special occasion in order to build up a highly interesting and comprehensive program were covered. The contributions submitted to the Congress included 6 plenary lectures, 84 section lectures, and more than 240 posters. This Congress, followed the excellent international tradition, was attended by close to 1000 domestic and foreign participants. We received 326 short paper submissions from more than 25 countries. These numbers show that our Congress is aiming for the highest scientific standards, and that it can be considered a well-established venue for researchers in the broad fields of Pharmaceutical sciences and practice.

We would like to thank all internationally prominent researchers for their contribution to reinforcing the overall quality of the Congress. They give the state of the art of the recent advances in the field of pharmacy research.

Sincere thanks to the hosts of the Sixth Congress of Pharmacy in Macedonia with International participation, Macedonian Pharmaceutical Association and Faculty of Pharmacy, Ss Cyril and Methodius University in Skopje for their vision and commitments.

We acknowledge the sponsoring companies: the platinum sponsor AD ALKALOID, Skopje, the golden sponsor PLIVA, the silver sponsor EUROFARM and the bronze sponsor SEPTIMA, for the permanent support to our efforts during the organization.

We would also like to thank our members of the Scientific Committee for their volunteer time and dedication to the critical peer review process and in the organization of the program. We also wish to thank all the members of the Organizing Committee, whose work and commitment was invaluable.

On behalf of the Advisory and Scientific Committees, we would like to especially thank the authors, whose work was the essential part of the congress and contributed to a very successful event. Besides the many academic staff and professionals who contributed to the success of the Congress, we are grateful to the students who participated with oral presentations and posters.

The pharmaceutical sciences continue to grow as dynamic scientific interdisciplinary fields. We believe that published short communications will be an excellent source of scientific material in the fast evolving fields in Pharmaceutical sciences and practice.

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The present issue of *Macedonian Pharmaceutical Bulletin* is a special issue of the 6th Congress of Pharmacy in Macedonia with international participation.

This issue of *Macedonian Pharmaceutical Bulletin* contains short papers accepted by the scientific committee for the presentation at the Congress.

The authors are fully responsible for the contents of their short papers.

All reviewers that were involved in the short papers revision process are sincerely acknowledged.



A rapid and validated reverse phase liquid chromatographic method for *in vitro* dissolution test for determination of bromazepam in tablet formulations

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Introduction

Disorders that involve anxiety are the most common mental disturbances. Many of the anti-anxiety medicines also cause some sedation, so the same medicine is often functioning clinically as both, anxiolytic and hypnotic agent. Benzodiazepines are the most widely used anxiolytic medicines. They have largely replaced barbiturates in the treatment of anxiety, because the benzodiazepines are safer and more effective. Anxiety is an unpleasant state of tension, apprehension, a fear that seems to arise from a sometimes unknown source. The physical symptoms of severe anxiety are similar to those of fear (such as tachycardia, sweating, trembling, and palpitations) and involve sympathetic activation. Episodes of mild anxiety are common life experiences and do not warrant treatment. However, the symptoms of severe, chronic, debilitating anxiety may be treated with antianxiety medicines (sometimes called anxiolytic or minor tranquilizers) and/or some form of behavioral or psychotherapy.

Bromazepam is a benzodiazepine (BZD) generally used for a number of medical reasons, it is an intermediate-acting tranquiliser (Ashton, 2005), prescribed for the treatment of moderate to severe anxiety and panic attacks for the short-term treatment of insomnia. It has been widely used in psychiatry disorders for four decades, with selective anxiolytic, anticonvulsant, myorelaxant and hypnotic actions. It acts on the central neural system as an inhibitor of the neurotransmitter gamma aminobutyric acid (GABA) (Nascimento et al., 2012).

Bromazepam is an active substance that belongs to class of 1,4-benzodiazepine and chemically corresponds to 7-bromo-1,3-dihydro-5-(2-pyridyl)-2H-1,4-benzodiazepine-2-one, C₁₄H₁₀BrN₃O (Ph.Eur., 2010). It is a controlled psychotropic substance-B1 class according to the National Agency of Sanitary Vigilance in Brazil (ANVISA), with the DCB identification numbers: 01366, DCI: 2692 and CAS: 1812-20-2. The solid dosage form (tablet) is the widespread used and prescribed in clinical practice. The solid dosage form presents problems associated to the bioavailability (FDA, 2003). The absorption of active substance from the solid dosage form for oral application depends on the solubility and dissolution in physiologic liquids and its permeability through the gastrointestinal tract, factors that influence directly its bioavailability and subsequent pharmacological effects. The biotransformation from solid into absorbable form depends on its dissolution in organic liquids; therefore, dissolution tests became an essential parameter to determine the properties of biopharmaceutical formulations in order to predict their quality. The quality of pharmaceutical formulations is important in financial and ethical terms because it is directly associated with the patient's health. Thus, there is a real need for the development of dissolution tests able to predict *in vivo* physiological conditions.

Materials and methods

Dissolution test is a standardized method for measuring the rate of active substance release from a dosage form (FDA, 1997). The test was performed on ERWEKA DT 700, apparatus 2 (paddle), using 0.1 M HCl as a dissolu-

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tion medium, in volume of 500 ml, at 37°C, with 75 rpm for 45 minutes.

The quantity of the dissolved bromazepam was determined using analytical method based on High Performance Liquid Chromatography (HPLC). Validation of the method was performed on Shimadzu Nexera HPLC system.

To optimize chromatographic parameters several mobile phase compositions were tested in this method. A satisfactory separation, good peak symmetry and optimal retention time was obtained using mobile phase consisting of a mixture of methanol, acetonitrile and potassium dihydrogen phosphate buffer (11.33 g/l of KH_2PO_4 , pH 7.0 adjusted with KOH, 0.5 M) in ratio of 45:5:50 (v/v/v), at flow rate of 1.0 ml/min. A LiChrospher RP Select B column (125 × 4.0 mm, 5µm) was used as stationary phase with temperature of column oven, 50 °C. The elution was monitored at 239 nm.

Results and discussion

A simple reverse phase HPLC method for *in vitro* dissolution test was developed and validated for the determination of bromazepam and its release from pharmaceutical dosage form. Several high-performance liquid chromatographic (HPLC) methods have also been reported for the determination of bromazepam and other BZDs (Sruthi et al., 2013). Chromatogram showed a peak of bromazepam (BZP) at retention time of 3.50 ± 0.1 min. The most suitable mobile phase was selected on the basis of time required for the analysis and the sensitivity of the method. The method was validated according to ICH Q2 guideline with respect to specificity, linearity (with correlation coefficient of 0.999), accuracy, precision, robustness, solution stability and filter paper compatibility. All results of the validation parameters were within the limits of ICH guidelines (ICH, 2005). The benefits of the proposed method include simple preparation of the solutions for the analysis and usage of readily available solvents.

Conclusion

The proposed method is simple, rapid, accurate, precise and specific without interference of excipients. The short chromatographic run time allows the analysis of a large number of samples in short period of time. Therefore, it is suitable for the routine analysis of bromazepam in pharmaceutical dosage forms and it could be used for the rapid and reliable determination of dissolved bromazepam in tablet formulations. The present study was focused on minimizing method limitations and developing a simple and economic method for determination of dissolved bromazepam from tablet dosage form.

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